REMARKS

The Final Office Action mailed July 7, 2002, has been received and reviewed. Claims 1 and 3 through 45 are currently pending in the application. Claims 1, 3-7, 12-14, 19, 20, 22, 24-26, and 39-45 stand finally rejected, while claims 8-11, 15-18, 21-23, 27-32 and 34-38 are objected to. Applicants respectfully request reconsideration of the application in light of the amendments and remarks set forth herein.

Objections

Claims 8-11, 15-18, 21-23, 27-32 and 34-38 are objected to in the Office Action as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants note with appreciation the indication of allowable subject matter and respectfully submit that, except for claim 15, each of the claims objected to has been rewritten and no longer depends from a rejected base claim. Applicants respectfully submit, therefore, that claims 8-11, 16-18, 21-23, 27-32 and 34-38 are in condition for allowance.

Regarding claim 15, Applicants respectfully submit that the Office Action leaves the status of the claim ambiguous. In the Office Action, claim 15 is objected to as being dependent from a rejected base claim. However, claim 15 is written in independent form, and Applicants respectfully submit that claim 15 is allowable over the references cited in the Office Action. Applicants, therefore, respectfully request clarification regarding claim 15.

35 U.S.C. § 102 Rejections

Claims 1, 3-7, 12-14, 19, 20, 24-26, and 39-45 stand finally rejected under Section 102(b) as being anticipated by one of Clark et al. (U.S. 5,374,620) and Sparks et al. (U.S. 4,952,402). However, Applicants respectfully note that claims 1, 3-7, 12-14, 19, 20, 24-26, and 39-45 have been cancelled herein without prejudice or disclaimer. Therefore, Applicants respectfully submit that the rejection of such claims is no longer relevant and Applicants respectfully request that the rejection of claims 1, 3-7, 12-14, 19, 20, 24-26, and 39-45 under Section 102(b) be withdrawn.

Clarification Regarding Claim 22

Applicants respectfully note that that in the Office Action Summary claim 22 is both objected to and rejected. However, the remarks set forth in the Detailed Action indicate that claim 22 is simply objected to as dependent upon a rejected claim. Neither of the rejections set forth in the Detailed Action indicate that claim 22 stands rejected in light of the references cited therein. Applicants, respectfully submit that claim 22 is allowable over the references cited in the Detailed Action and respectfully note that claim 22 is herein amended to eliminate any dependency from a rejected claim. Applicants, therefore, respectfully submit that claim 22 is in condition for allowance and respectfully request clarification regarding the status of claim 22.

Entry of Amendments

The proposed amendments to claims 8-11, 15-18, 21-23, 27-32 and 34-38 above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application. Further, the amendments place the application in condition for allowance and do not raise new issues or require a further search. Finally, if the Examiner determines that the amendments do not place the application in condition for allowance, entry is respectfully requested upon filing of a Notice of Appeal herein.

Conclusion

Claims 8-11, 15-18, 21-23, 27-32 and 34-38 are believed to be in condition for allowance, and notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, she is respectfully invited to contact Applicants' undersigned attorney.

Respectfully Submitted,

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Version With Markings to Show Changes Made

8. (Amended) [The vehicle of claim 1] A stable non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same, the ratios of the two components are in the range of 40:60 to 60:40, and the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

9. (Amended) [The vehicle of claim 4] A stable non-aqueous single phase biocompatible viscous vehicle which comprises three components selected from the group consisting of solvent, surfactant, and polymer, wherein the components are not the same, wherein the ratios of the components are in the range of about 30% to about 50% for solvent, about 5% to about 20% for surfactant, and about 5% to about 60% for polymer, and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

10. (Amended) [The vehicle of claim 4] A stable non-aqueous single phase biocompatible viscous vehicle which comprises three components selected from the group consisting of solvent, surfactant, and polymer, wherein the components are not the same, wherein the polymer is polyvinlypyrrolidone, the surfactant is glycerol monolaurate, and the solvent is lauryl lactate, and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

11. (Amended) [The vehicle of claim 4] A stable non-aqueous single phase biocompatible viscous vehicle which comprises three components selected from the group consisting of solvent, surfactant, and polymer, wherein the components are not the same, wherein the polymer is polyvinlypyrrolidone, the surfactant is polysorbate, and the solvent is lauryl lactate, and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

16. (Amended) [The formulation of claim 14 wherein said formulation] A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate and is stable at body temperature for extended periods of time, the stable non-aqueous viscous protein formulation comprising:

a) at least one beneficial agent; and

b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

17. (Amended) [The formulation of claim 14 which comprises] A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising:

a) at least about 0.1% (w/w) beneficial agent; and

b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

18. (Amended) [The formulation of claim 14 which comprises] A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising:

a) at least about 10% (w/w) beneficial agent; and

b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

21. (Amended) [The formulation of claim 14 which] A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate and is stable at 65° C for at least about 2 months, the stable non-aqueous viscous protein formulation comprising:

a) at least one beneficial agent; and

b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

22. (Amended) [The formulation of claim 14 which] A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate and is stable at 37° C for at least about 3 months, the stable non-aqueous viscous protein formulation comprising:

a) at least one beneficial agent; and

b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

23. (Amended) [The formulation of claim 14 which] A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate and is stable at 37° C for at least about one year, the stable non-aqueous viscous protein formulation comprising:

a) at least one beneficial agent; and

b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

27. (Amended) [The formulation of claim 14 comprising] A stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising:

a) a beneficial agent which has been dried to a low moisture content prior to incorporation in [said] the stable non-aqueous viscous protein formulation; and

b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

28. (Amended) [The formulation of claim 14] A non-aqueous viscous protein formulation which is stable after sterilization and is capable of being uniformly dispensed over an extended period of time at a low flow rate, the non-aqueous viscous protein formulation comprising:

a) at least one beneficial agent; and

b) a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

29. (Amended) A method for preparing [the stable single phase viscous vehicle of claim 1, 3, or 4] a stable non-aqueous single phase biocompatible viscous vehicle, the method comprising the steps of (1) selecting two components from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same; (2) blending the [ingredients] two components at elevated temperature under dry conditions to allow them to liquefy[,]; and [(2)] (3) allowing the liquid from step [(1)] (2) to cool to room temperature such that a stable non-aqueous single phase biocompatible viscous vehicle formed exhibits a viscosity between about 1,000 and about 10,000,000 poise.

30. (Amended) A method for preparing [the stable formulation of claim 14] a stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the method comprising:

combining [the single phase viscous vehicle and], under dry conditions, a beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise;

blending them under vacuum at elevated temperature to uniformly suspend the beneficial agent in the vehicle[,];

and allowing the formulation to cool to room temperature.

31. (Amended) [The method of claim 30 wherein] A method for preparing a stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the method comprising:

combining, under dry conditions, at least about 0.1% (w/w) of a beneficial agent [is suspended in said vehicle] in a non-aqueous single phase biocompatible viscous vehicle, wherein the vehicle comprises two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise;

blending the beneficial agent and non-aqueous single phase biocompatible viscous vehicle under vacuum at elevated temperature to uniformly suspend the beneficial agent in the vehicle; and

allowing the formulation to cool to room temperature.

32. (Amended) [The method of claim 30 wherein] A method for preparing a stable non-aqueous viscous protein formulation that is capable of being uniformly dispensed over an extended period of time at a low flow rate, the method comprising:

suspending at least about 10% (w/w) beneficial agent [is suspended in said vehicle] in a non-aqueous single phase biocompatible viscous vehicle, wherein the vehicle comprises two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise under dry conditions;

blending the beneficial agent and non-aqueous single phase biocompatible viscous vehicle under vacuum at elevated temperature to uniformly suspend the beneficial agent in the vehicle; and

allowing the formulation to cool to room temperature.

34. (Amended) [The method of claim 33 wherein said administration is parenteral administration] A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent, the method comprising:

parenterally administering a therapeutically effective amount of a stable non-aqueous viscous protein formulation capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising the beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise.

35. (Amended) [The method of claim 33 wherein said administration is] A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent, the method comprising:

providing a stable non-aqueous viscous protein formulation capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising the beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise; and

administering the stable non-aqueous viscous protein formulation to a subject, wherein said administering is long-term and continuous [administration].

36. (Amended) [The method of claim 33 wherein said administration is accomplished] A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent, the method comprising:

providing a stable non-aqueous viscous protein formulation capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising the beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise; and

administering the stable non-aqueous viscous protein formulation to a subject, wherein said administering by use of an implantable drug delivery system.

37. (Amended) [The method of claim 33 wherein said] A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent, the method comprising:

providing a stable non-aqueous viscous protein formulation capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising the beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise; and

administering the stable non-aqueous viscous protein formulation to a subject, wherein said administering includes daily administration of the stable non-aqueous viscous protein formulation and continues for a period selected from the group consisting of about 3 months, about 6 months, and about 12 months.

38. (Amended) [The method of claim 37 wherein said daily administration] A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent, the method comprising:

providing a stable non-aqueous viscous protein formulation capable of being uniformly dispensed over an extended period of time at a low flow rate, the stable non-aqueous viscous protein formulation comprising the beneficial agent and a non-aqueous single phase biocompatible viscous vehicle comprising two components selected from the group consisting of solvent, surfactant, and polymer, wherein the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise; and

administering the stable non-aqueous viscous protein formulation to a subject, wherein said administering is accomplished using an implantable drug delivery system and includes administering the stable non-aqueous viscous protein formulation daily for a period selected from the group consisting of about 3 months, about 6 months, and about 12 months.